[redacted]

P-18-0379

Chemical Name: [redacted]

Generic Name: Cashew nutshell liquid polymer with Epichlorohydrin, formaldehyde, phenol, amines and glycol.,

CASRN: [redacted]

ASSIGNMENTS	NAME	DATE
SAT Chair	Becky Daiss	10/19/2018
HH Hazard Assessor (A)	Amy Benson	10/19/2018
HH Hazard QC Reviewer (A)	Iris Camacho	10/22/2018
HH Risk Assessor FOCUS (B)	Amy Benson	11/01/2018
HH Risk QC Reviewer (B)	Chris Brinkerhoff	10/31/2018

Human Health Report Status:		DATE COMPLETED
X	HAZARD DRAFT- Pending Review	10/19/2018
X	HAZARD REVIEWED	10/22/2018
X	HAZARD FINAL	10/22/2018
X	RISK DRAFT- pending review	10/31/2018
X	RISK REVIEWED	10/31/2018
X	RISK-FOCUS FINAL- Uploaded	2/27/2019
X	POST-FOCUS UPDATE DRAFT	2/28/2019
X	POST-FOCUS UPDATE FINAL- Uploaded	2/28/2019

[redacted]

1 HUMAN HEALTH SUMMARY

EPA estimated the human health hazard of this chemical substance based on other structural information.

Based on the hazard determination and available qualitative risk information, EPA did not identify risks for the PMN substance when adequate PPE are used.

1.1 Hazard Summary

1.1.1 Absorption / Metabolism

Absorption of the intact PMN (representative structure MW [redacted]) is nil all routes (pchem). Uncertain absorption of the LMW [redacted] < 500 [redacted] < 1000) which are not identified.

1.1.2 Structural Alerts

N/A

1.1.3 Hazard Concerns

Cationic binding to the lungs as well as irritation to the eyes and skin hazards are identified due to the multiple [redacted] groups. Sensitization hazard is identified due to the cashew nut oil component. There may be health concerns for potential low molecular weight components (e.g., [redacted]) if made differently. Note, however, that the fraction less than 500 mw is [redacted]%; therefore, these concerns are expected to be minimal for the manufacturing process identified for the current submission.

1.1.4 Hazard Summary (narrative)

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and by comparing it to structurally analogous chemical substances for which there is information on human health hazard. Absorption is estimated to be nil through the skin and poor to moderate through the lung and gastrointestinal (GI) tract based on physical/chemical properties. EPA identified lung effects (i.e., Inflammation, metaplasia and fibrosis) hazards based on cationic binding to the lungs. The multiple amine groups in the PMN substance is a structural alert for irritation (eyes, skin). EPA also identified sensitization as a hazard due to the cashew nut oil component. There may be health concerns for potential low molecular weight components (e.g., [redacted], [redacted]) if made differently. Note, however, that the fraction less than 500 mw is [redacted]%; therefore, these concerns are expected to be minimal for the manufacturing process identified for the current submission.

1.2 Exposure and Risk Summary

1.2.1 Workers

Dermal Route

Skin and eye irritation and skin sensitization hazards were identified based on a structural alert. Risks for these hazard endpoints were not quantified due to a lack of dose-response for the hazard.

[redacted]

Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including impervious gloves and eye protection.

Inhalation Route

Risks were not identified for workers via the inhalation route because exposure is expected to be negligible.

1.2.2 General Population

Risks were not evaluated because general population exposures are expected to be negligible.

1.2.3 Consumers

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.

1.3 Potentially Useful Information:

1.3.1 Assumptions and Uncertainties

Absorption of the PMN is based on p-chem properties.

There are no measured toxicity data on the PMN substance itself.

Health effects are identified based on structure.

All predicted environmental releases to air, incineration, and/or landfill are expected to be negligible

No reasonably anticipated consumer exposures

1.3.2 Potentially Useful Information

Potentially useful information would inform understanding of:

- Pulmonary effects
- Skin irritation/corrosion
- Eye irritation/corrosion
- Skin sensitization

[redacted]

2 HUMAN HEALTH HAZARD- PART A

2.1 Chemistry Summary

PMN: P-18-0379	Submitter: [redacted]		Manu.	Import
Max. PV (KG): [redacted]	Binding Option Marked:			X
MW: [redacted]	[redacted]	% < 500 [redacted]	% <1000	CASN[redacted]

PMN Structure	Prop.	Meas.	Est.
[redacted]	MP		
	BP		>400
	Pres.		at 760 mm Hg
	VP		<0.000001
	S-H2O		<0.000001
	log P		

[redacted]	Analogues: [redacted]
USE: [redacted]	other_uses No other uses were found for the PMN material.

2.1 SAT Summary

2.1.1 PMN Health Rating

1-2

2.1.2 SAT Key Words

IRRITATION (EYES, SKIN), LUNG EFFECTS, SENSITISATION

2.1.3 Absorption

Absorption of the intact PMN (representative structure MW[redacted]) is nil all routes (pchem).
Uncertain absorption of the LMW ([redacted] < 500[redacted] < 1000) which are not identified.

[redacted]

2.1.4 SAT Health Summary

There is concern for cationic binding to the lungs as well as irritation to the eyes and skin due to the multiple [redacted] groups. There is concern for sensitization due to the cashew nut oil component. There may be health concerns for potential low molecular weight components (e.g., [redacted]). Also, the polymer could be made differently with a higher percentage of LMW fractions.

2.1.5 Exposure Routes of Interest

Route of Interest	
X	Inhalation
X	Dermal
X	Ingestion

2.2 Toxicity Data

2.2.1 PMN Data (study summary, POD, same-as)

None

2.2.2 Analogue/Metabolite Data (chemical, structure, study summary, POD)

No close analogues with data were identified. Note that some chemicals < 500 MW ([redacted] and [redacted]) were identified, these were not used for a POD because there was just [redacted] % < 500.

2.2.3 SDS Data (composition, hazard identification, toxicological information)

The SDS appears to be for the submitted PMN because the tradename (identified as [redacted]) in the identification section of the SDS is the same as the name listed in the PMN submission (Section B, #5, page 6). The composition section of the SDS notes that less than [redacted]% of the product consists of [redacted].

Section 11 – Toxicological Information

This identifies the product as irritating to eyes, mucous membranes and skin as well as sensitizing through inhalation and skin contact. This section also includes a general statement that the PMN is 'harmful.'

[redacted]

2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS08 Health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**
· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms**

GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**
Ethylenediamine
· **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

(Contd. on page 2)

2.2.4 Other Information

Conclusion from [redacted] (Same as case):

Type of Concern:	Health	Eco	Comments
Level of Concern:	1-2	1	**Health:** Concerns for sensitization, irritation and cationic lung binding

Keywords:

Keywords: Cationic lung binding Sens Irr- E S

Health:

Hazard Assessment: Absorption: Parent compound is NIL all routes, Low MW fractions are poor all routes based on p-chem properties. There is concern for cationic binding to the lungs as well as irritation to the eyes and skin due to the multiple amine groups. There is concern for sensitization due to the cashew nut oil component.

The following analogues were searched in AIM but had no relevant data:

[redacted]

2.3 Human Health Category (From US EPA 2010 document)

Not applicable

2.4 Point of Departure Selected and Basis

2.4.1 POD for Lung Cationic Binding [For Inhalation Route Only]

POD type (NOAEL/LOAEL): LOAEC

POD Chemical: [redacted]

POD Route: Inhalation

POD Endpoint: Inflammation, metaplasia and fibrosis

POD Value: 1.6 mg/m^3

POD Basis: Four week study on [redacted] in Sprague Dawley rats (sex not reported), 6 hours/day, 5 days/week with a 2 day recovery period.

POD Benchmark MOE: 1,000 (10 for LOAEC to NOAEC * 10 interspecies UF * 10 intraspecies UF)

Reference: [redacted]

[redacted]

3 HUMAN HEALTH RISK (PART B)

3.1 USES and EXPOSURES

3.1.1 Uses

[redacted]

3.1.2 Worker Exposure

3.1.2.1 Inhalation

negligible, VP < 0.001 torr and generation of respirable PMN not expected.
Note the submitter indicates that the PMN is mixed prior to the coating operation. During the mixing step, the PMN is reacted/consumed, therefore there are no releases or exposures associated with the coating operation.

3.1.2.2 Dermal

High-end PDR, exposure to [redacted]
[redacted] mg/day over [redacted] days/year, [redacted] workers

3.1.3 General Population Exposure:

No identified general population exposures (expected to be negligible)

3.1.4 Consumer Exposure

No identified consumer exposures

3.2 RISK CALCULATIONS

3.2.1 Worker Calculations

Risks were not quantified because the exposure (dermal) is associated with hazards that have lack of dose-response information or exposure (inhalation) is negligible. Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including impervious gloves and eye protection.

3.2.2 General Population Calculations

Risks were not evaluated because general population exposures are not expected/negligible.

3.2.3 Consumer Calculations

Risks to consumers were not evaluated because consumer use was not identified as a condition of use.